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OCT 1 1 2001

SELECT MEDICAL SYSTEMS INC.

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-401)
9200 Corporate Boulevard
Rockville MD 20850

510(k) Summary

Submitter	Select Medical Systems, Inc 30 Winter Sport Lane Williston VT 05495
	Ph (802) 862-1017 Fx (802) 862-3767
Contact person	Monique Girard
Date of Summary	08-27-2001 MM DD YYYY
Device prorietary name	TheCurve™
Device common/usual name	Intrauterine insemination catheter
Device classification name	Intrauterine insemination cannula
Predicate device name	Select IUI®

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92(c).

Intended use

As the Select IUI® (predicate device), TheCurve™ (new device) is a single use, sterile, disposable, flexible catheter designed to be used for intrauterine artificial insemination.

Description of new device and comparison with predicate device.

TheCurve, such as the Select IUI, comprises a long clear polyethylene tube that is tightly surrounded on three quarters of its proximal length by an outer, clear polypropylene sheath. This leaves 4.5 cm of the inner polyethylene tube exposed at the distal end of the device. The proximal inner tube and outer sheath circumferences are molded directly onto the distal end of a luer lock hub so that only the lumen of the inner tube can provide a channel for flow. This design results in a single-channel catheter with two segments each having different degrees of flexibility.

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The extreme distal tip of TheCurve™ is open as compared to the extreme distal tip of the Select IUI® which is closed and has two side openings.

Both TheCurve and Select IUI have six (6) coloured graduation markings placed at 5, 6, 7, 8, 9, and 10 cm distance from the extreme distal tip of the catheter.

The distal portion of TheCurve is curved while the distal portion of the Select IUI is straight.

Product specifications – Summary

	TheCurve (new device)	Select IUI (predicate device)
Length	17.2 cm (effective) 19.9 cm (overall)	17 cm (effective) 20 cm (overall)
ID (inner diameter)	1.1 mm for effective length	1.6 mm for effective length
OD (outer diameter)	2.6 mm stepped down to 1.6 mm for distal 4.5 cm of length	2.6 mm stepped down to 2.1 mm for distal 4.5 cm of length
Graduation marks	Identical for both devices	
Design	Identical for both devices. The distal portion, however of TheCurve is curved while the distal portion of the Select IUI is straight.	
Function	Identical for both devices	
Materials	Identical for both devices	
Intended use	Identical for both devices	

Substantial equivalence

TheCurve is substantially equivalent in safety and effectiveness to the Select IUI as both devices are identical in terms of raw materials, intended use, function, graduation markings and they have a similar design. There are three minor differences: (i) TheCurve is 1 mm shorter than the Select IUI; (ii) TheCurve has an ID of 0.5 mm smaller than the Select IUI; (iii) and, the distal portion of TheCurve is slightly curved to ease its insertion into the cervical os and through the cervical canal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2001

Ms. Monique Girard
Regulatory Affairs Manager
Select Medical Systems, Inc.
30 Winter Sport Lane
P.O. Box 966
WILLISTON VT 05495-0966

Re: K012935
Trade/Device Name: TheCurve™ Item 507
Intrauterine Insemination Cannula
Regulation Number: 21 CFR 884.5250
Regulation Name: Cervical Cap
Regulatory Class: II
Product Code: 85 MFD
Dated: August 29, 2001
Received: August 31, 2001

Dear Ms. Girard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

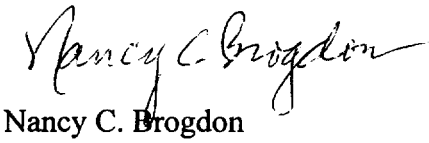
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION C – PAGE 1 OF 1

STATEMENT OF INDICATIONS FOR USE

510(k) number (if known) K012935

Device name TheCurve™

Indication(s) for use Intrauterine artificial insemination

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012935

Prescription Use ✓